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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,975	06/29/2001	Mark R. Schmitt	AM100341	9267
25291	7590	05/26/2004	EXAMINER	
WYETH PATENT LAW GROUP FIVE GIRALDA FARMS MADISON, NJ 07940			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,975

Applicant(s)

SCHMITT ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6-8, 10-12, 14-20, 22, 67, 70, 74-77, 79-81, 83-85, 87-93 and 95-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6-8, 10-12, 14-20, 67, 70, 74-77, 79-81, 83-85 and 87-93 is/are rejected.
- 7) ☒ Claim(s) 22 and 95-97 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>#8</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment of 04-11-04 has been fully considered. Claims 1 and 70 have been cancelled, and therefore, the previous 112/1st paragraph has been obviated, and withdrawn herein. However, a search and another review of the pending claims yield the following new grounds of rejection.

Claims 1, 5, 9, 13, 21, 23-66, 68, 69, 71-73, 78, 82, 86, and 94 have been cancelled. Therefore, only claims 2-4, 6-8, 10-12, 14-20, 22, 67, 70, 74-77, 79-81, 83-85, 87-93, and 95-97 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2-4, 6-8, 10-12, 14-20, 67, 70, 74-77, 79-81, 83-85, and 87-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 2-4, 6-8, 11, 12, 14-18, 70, 75-77, 79-81, 84, 85, 87, 89-91 are indefinite because they recite moieties that are "*optionally substituted*" without reciting the intended substituents. In the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term

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“substituted” renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. Claims 10, 19, 20, 67, 74, 83, 88, 92, and 93 are rejected as being dependent on claims 2, 70, or 75.

c. Claims 2-4, 6-8, 10-12, 14-20, 67 are rejected because they recite (or refer to) a “*method of treating or inhibiting the growth of cancerous tumor cells and associated diseases*”. The metes and bounds of “*associated diseases*” are unclear. Many times, cancer patients have secondary infections due to chemotherapy. Thus, it is unclear whether the claimed method would include secondary infections (i.e., secondary bacterial, fungal or viral infections) as well.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 70 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. **5,948,783**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fungicidal composition recited in claim 5 of US'783 anticipates the pharmaceutical composition recited in claim 70 of this application.
3. Claim 70 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-13 of U.S. Patent No. **6,020,338**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fungicidal composition recited in claims 8-13 of US'338 anticipates the pharmaceutical composition recited in claim 70 of this application.
4. Claim 70 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6 of U.S. Patent No. **6,117,876**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fungicidal composition recited in claims 4-6 of US'876 anticipates the pharmaceutical composition recited in claim 70 of this application.
5. Claim 70 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. **6,255,309 B1**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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fungicidal composition recited in claim 4 of US'309 anticipate the pharmaceutical composition recited in claim 70 of this application.

6. Claim 70 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. **6,297,251 B1**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fungicidal composition recited in claim 9 of US'251 anticipate the pharmaceutical composition recited in claim 70 of this application.


Claim Objections

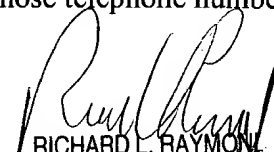
7. Claims 22, and 95-97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The species in said method claims are not found in the prior arts of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


T. Truong
May 21, 2004


RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624